REMARKS

Reconsideration is requested.

Claims 1-28 are pending.

A response to the Request of January 24, 2005 is requested.

The Section 112, second paragraph, rejection of claims 1-28 is obviated by the above amendments.

Specifically, the claims have been amended to further define the inter-relationship of the steps of independent claims 1 and 14, which is understood to be the basis for the rejection.

Step (iii), for example, now recites the inputting of alleles present in said subject, wherein said alleles are at one or more of the genetic loci of said first dataset. Step (iii) further clearly states that the invention uses allelic data of individual subjects, which may be provided for input into the method of claim 1, for example, from any suitable source. The Examiner is urged to appreciate however that it is not an essential feature of the claims as to the particular method by which such data is obtained. For example, it is possible that such data may be obtained in a different jurisdiction, or at a different time point, prior to performance of the claimed methods.

In regard to step (iv), the Examiner is understood to have suggested that an element is missing in step (i) such that it is allegedly unclear whether the risk factors identified in step (iv) are performed by comparing the individual's data with a set of generic, known data generated from a variety of samples. Step (iv) refers to correlating the alleles present in the subject with the risk factors provided by the first dataset.

Steps (iv) and (i) are believed to be clearly linked and understandable by one of ordinary skill in the art.

The applicants further submit that step (i) as such is not missing any particular elements; various risk factors associated with alleles of genes may be derived from any available source, as taught extensively throughout the present application, such as for example, at pages 17-30.

In regard to step (v), the Examiner is understood to have queried how the data of this step relates to the dataset of step (ii). Step (v) refers to matching the risk factor with a lifestyle recommendation from the second dataset.

In regard to step (vi), the Examiner is understood to have stated that it is allegedly unclear that the second dataset is a dataset which is different from that of the patient sample. Step (vi) refers to the recommendations determined in step (v), which is submitted to be clear and definite. In particular, the personalized lifestyle plan is based on recommendations matched to the individuals allelic profile.

The claims are submitted to be definite and withdrawal of the Section 112, second paragraph, rejection of the same is requested.

The Section 103 rejection of claims 1-28 over Brown (U.S. Patent No. 5,985,559), in view of Perera (Carcinogenesis (2000) Vol. 21, pp 517-524), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

Attached are schematic flowcharts of the present invention and of Brown. In respect of the instantly claimed invention, applicants make no representation that the

specific alleles, risk factors or recommendations are essential to every embodiment of the invention; nonetheless they are illustrative of the general principle.

Thus, in the present invention there are provided the first and second datasets (downward diagonal hatched box and vertical hatched box, respectively). The first dataset comprises information about a number of loci (A, B, etc) and alleles at those loci (A1, A2, etc), wherein at least one allele of each loci is associated with a risk factor (A1, B2, B3, etc). The second dataset matches each risk factor with a lifestyle recommendation (see vertical hatched box).

A third dataset, i.e. the specific loci present in a subject, is obtained (upperward diagonal hatched box) and this dataset is inputted into the system. The system then matches those subject-specific loci with the lifestyle recommendations appropriate for any risk-factors identified. Those recommendations are generated as a personalized plan for that patient.

Once the data from the patient is inputted into the system, the generation of the lifestyle advice plan requires no further patient input. This is in contrast to Brown, which relates to an iterative process, as illustrated in the attached flowcharts.

In particular, Brown provides that a "health monitor" receives inputs of a patient-specific gene sequence. The gene sequence is then transmitted from the health monitor to a gene database (Fig. 4 (**28**); Fig. 8 (**102**); flowchart (A)). The gene database then generates a "script" (Fig. 8 (**26**)), via a "script database" (**104**), associated with the gene. The "script" is then presented to the patient (e.g. Fig. 7; flowchart (B)).

Thus the "scripts" of Brown cannot be equated to the personalised lifestyle advice plan of the present invention. In particular, the scripts of Brown are elements

which require a patient response in order for the system to function. Thus in the attached flowchart, the system illustrated as "Brown (B)" will remain static until a patient input into the health monitor has been provided. Step (C) of the attached Brown flowchart will only occur once a response to the script has been generated. Thus at column 4 lines 60 – column 5 line 5 it is stated:

> "However, if based on gene sequence 21, it is likely the patient does have a predisposition for a disease, script 26 will contain questions about the patient's environment or lifestyle. The ***patient or clinician can then answer the questions on script 26*** and send the response back over network 30 to database 20. Database 20 has the ability to generate another dynamic script 27, based on the patient's response. ***In other words, the answers to questions in script 26 are used to assess the patient's status*** (this may be performed by a doctor or an appropriate health-care decision-making program) and generate dynamic script 27 to gain better insight or more information about the patient." [Emphasis added]

The iterative nature of the Brown process is further emphasised at column 6 line 30 *et seq* which details the nature of the system of that disclosure. Thus at column 6 line 50-51 it is again emphasised that a script (1, X) is generated ***after*** the analysis of a gene sequence in the form of a question "to be displayed and answered" by the patient. A reply to the script is essential for the process to proceed. The reply is then used in an iterative manner to generate further scripts.

The response to the scripts in Brown are deposited in a "Geno-Pheno Map". This cannot be equated to a personalised lifestyle advice plan of the present invention. In particular, at column 7 lines 36-48 Brown teaches that the:

> "... geno-pheno map 106 can be used to build up a dynamic genotype-phenotype knowledge base 108. The

> information in base 108 represents the current state of knowledge about genotype to phenotype mapping and as such is an extremely useful tool for any persons involved in gene research. As indicated, the up-to-date information from knowledge base 108 can be distributed to research institutions to aid in developing new treatments, monitoring programs and prognoses. Doctors working at hospitals and clinics can use the current information in their practices to develop better patient-specific regimens and treatments. Also, record files can be created to evidence progress in the field or for archival purposes."

Thus neither the "scripts" of Brown nor the "geno-pheno map" directly relate to the provision of a personalized lifestyle advice plan generated by analysis of allelic risk factors in a subject. On the contrary, Brown relates to the provision of an interactive system requiring continued patient inputs which in response to an iteratively-generated series of "scripts". Brown does not contemplate the provision of a specific lifestyle advice plan; rather the "geno-pheno map" appears to represent a general resource for ***physicians*** or "***persons involved in gene research***" to investigate disease processes and therapies.

In the present invention, the input of allelic data to the claimed system results in the generation of a personalized lifestyle advice plan without the requirement for the generation of gene-specific scripts requiring further patient (or physician) responses. It would not have been obvious from Brown to provide such a system as it is understood to be an essential requirement of Brown that "scripts" are generated in *response* to gene data, and that these scripts are replied to before the system proceeds further. This is in keeping with the overall teaching that the Brown disclosure relates to a "health monitor" (the term is used for example in claims 1, 2 and 5; at col. 1 line 13; col. 2 lines

40, 42/3, 46 & 66; col. 3 lines 1, 5, 10, 16, 18, 21, 24, 38 & 39; col. 4 line 47, 50, 56 & 57 as well as throughout columns 5, 6 and 7).

Thus, whereas Brown is intended to provide for on-going monitoring of a disease to allow a physician or other healthcare provider to review ongoing treatment, the present invention is directed to a customer-oriented output of personalized information relevant to lifestyle in general, rather than for the monitoring of any one specific disease. The output is provided without any ongoing need for the patient to reply to "scripts" generated in response to a gene data input.

No element of Perera would have motivated the ordinarily skilled person to alter the fundamental teaching of Brown that the provision of a "health monitor" requires iterative patient responses. Perera refers to the risk factors associated with certain forms of certain genes. Even if a person of ordinary skill in the art would have been motivated to combine this teaching with Brown, such genetic information would, at best, form part of the "gene database 102" of Brown. The person of ordinary skill in the art would have then needed to associate these genes with appropriate "scripts" for presentation to a subject, and replies to those scripts would have needed to be generated and assessed by the "geno-pheno map". Thus reference to Perera, while arguably being of assistance in the development of the Brown "gene database" provided no motivation to re-structure the health monitor system of Brown to arrive at the presently claimed invention.

The claims are submitted to be patentable over the cited art and withdrawal of the Section 103 rejection, along with a Notice of Allowance, are requested. The

Examiner is requested to contact the undersigned in the event anything further is required in this regard.

A personal interview with the Examiner and the Examiner's Supervisor is requested, prior to issuance of a further Action, in the event the Examiner believes the present application is not in condition for allowance after entry and consideration of the present Amendment. The Examiner is requested to contact the undersigned to arrange such an interview at a time convenient for the Examiners in the event the Examiner believes the present application is not in condition for allowance after entry and consideration of the present Amendment.

Respectfully submitted,

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